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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/616,303	07/14/2000	EDWARD L. SINOFSKY	101327-146	6336

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NUTTER MCCLENNEN & FISH LLP  
WORLD TRADE CENTER WEST  
155 SEAPORT BOULEVARD  
BOSTON, MA 02210-2604

EXAMINER

CHANG, CHING

ART UNIT PAPER NUMBER

3748

DATE MAILED: 12/30/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/616,303

Applicant(s)

SINOFSKY ET AL.

Examiner

Ching Chang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-24 is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☒ Claim(s) 9-12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 3, 2003 (Paper No. 11) has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. ***Claims 1-8 are rejected under 35 U.S.C. 102(b) as anticipated by Stevens et al. (US Patent No. 5,800,493).***

Stevens discloses an anchoring balloon device (1) comprising: a flexible elongate member (3) having an interior lumen extending therethrough for the delivery of an inflation fluid (25); an expand balloon (5) disposed about a portion of the flexible

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elongate member and in fluid communication with the lumen via at least one port; and a pressure-relief valve (a fluid fill valve 18) for regulating the pressure of fluid within the expandable balloon (See Col. 4 line 37 through Col. 5, line 10); wherein the pressure-relief valve is configured to open and release fluid in response to excess pressure exerted on the expandable balloon (See Col. 4, line 59 through line 67; Col. 5, line 16 through line 56); wherein the flexible elongate member is a catheter; wherein the pressure-relief valve provides irrigation; wherein the pressure-relief valve regulates pressure, further comprising means (30, 25, 18, 16, 14, 60) for inflating the expandable balloon; wherein the means for inflating the expandable balloon comprises a conduit defined in the interior lumen of the flexible elongate member for directing fluid into the expandable balloon; wherein the expandable balloon comprises a polymeric material (See Col. 4, line 29 through line 36); wherein the expandable balloon, when fully expanded, engages and is in direct contact with the tissue of a body lumen (6, 27)(See Col. 4, line 9 through line 13).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. ***Claims 1-8 are rejected under 35 U.S.C. 103(a) as being obvious over Stevens (US Patent No. 5,800,493) in view of Tamari (US Patent No. 5,429,483).***

Stevens discloses an anchoring balloon device (1) comprising: a flexible elongate member (3) having an interior lumen extending therethrough for the delivery of an inflation fluid (25); an expand balloon (5) disposed about a portion of the flexible elongate member and in fluid communication with the lumen via at least one port; and a pressure-relief valve (a fluid fill valve 18) for regulating the pressure of fluid within the expandable balloon (See Col. 4 line 37 through Col. 5, line 10); wherein the pressure-relief valve is configured to open and release fluid in response to excess pressure exerted on the expandable balloon (See Col. 4, line 59 through line 67; Col. 5, line 16 through line 56); wherein the flexible elongate member is a catheter; wherein the pressure-relief valve provides irrigation; wherein the pressure-relief valve regulates pressure, further comprising means (30, 25, 18, 16, 14, 60) for inflating the expandable balloon; wherein the means for inflating the expandable balloon comprises a conduit defined in the interior lumen of the flexible elongate member for directing fluid into the expandable balloon; wherein the expandable balloon comprises a polymeric material (See Col. 4, line 29 through line 36); wherein the expandable balloon, when fully expanded, engages and is in direct contact with the tissue of a body lumen (6, 27)(See Col. 4, line 9 through line 13).

With regard to section 103(a), Tamari discloses a varieties of pressure relief valves (281, 981, 231, 341, 441, 451, 531, 571, and 771 in Fig. 1), in the applications of an extracorporeal pumping. It would have been obvious to one having ordinary skill in

the art at the time the invention was made to have utilized the teaching from the Tamari reference to use any other suitable pressure relief valve for an extracorporeal circuit to control pressure therein, in the Stevens device, since the use thereof would provide an anchoring balloon device with the alternative pressure relief valve.

***Allowable Subject Matter***

6. Claims 13-24 are allowed.

7. Claims 9-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

8. Applicants' arguments filed on June 3, 2003 (Paper No. 11) have been fully considered but they are not persuasive, and are also moot in view of the new ground(s) of rejection, additionally.

Applicants argue that "Stevens does not teach or even suggest such a pressure-relief valve". Examiner disagrees. The reference to Stevens (See Col. 4, line 59 through line 67; Col. 5, line 16 through line 56) does read the amended claim language "

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the pressure-relief valve is configured to open and release fluid in response to excess pressure exerted on the expandable balloon " in claim 1.

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Wallace et al. (US Patent No. 5,591,497).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ching Chang whose telephone number is (703)306-3478. The examiner can normally be reached on M-Th, 7:00 AM -5:00 PM.

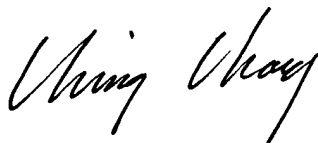
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Denion can be reached on (703)308-2623. The fax phone numbers for the organization where this application or proceeding is assigned are (703)872-9306 for regular communications and (703)872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1148.

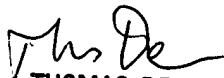
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Patent Examiner



Ching Chang  
December 18, 2003



THOMAS DENION  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700